Please replace the paragraph beginning at page 11, line 23 and ending at page 12, line 2 with the flowing paragraph:

When a separate interferant eliminating layer is used, it preferably contains a peroxidase enzyme which may or may not be preactivated. Such interferant eliminating layers are disclosed, for example, in U.S. Pat. No. 5,356,786 which discloses the structure and function of interferant eliminating biosensors. The glucose biosensor preferably contains lactate oxidase (LOX) in combination with peroxidase in the interferant eliminating layer. However, for biosensors used to detect lactate, glucose oxidase would be used with peroxidase. In a similar manner, the enzyme composition of the interferant eliminating layer may be altered for a specified function.

Please replace the paragraph beginning at page 16, line 34 and ending at page 17, line 3 with the flowing paragraph:

In addition to implanting the sending electrode in the body, fluid from the body, particularly fluid from the subcutaneous region, can be routed to an external sensor. it is preferred in this case to implant in the subcutaneous region a microfiltration giver and pull fluid to an evacuated container, the fluid traversing a cell containing the sensing electrode. Preferably this cell also contains a second electrode, e.g., a reference electrode which may serve also as a counter electrode. Alternatively, the reference and counter electrodes may be separate electrodes. In coulometric measurements only two electrodes, the sensing electrode and the counter electrode are required. The flow of body fluid may be pulsed or continuous. Other than an implanted microfiltration fiber, also a microdialysis fiber may be used, preferably in conjunction with a pump.

## **REMARKS**

The specification has been amended to update references to U.S. Patents, and to correct a minor typographical error.

Claims 31-78 are pending. The Examiner rejected claims 31-78 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,121,009. The Examiner also stated that a timely terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome the rejection.

The applicants disagree with the Examiner's characterization of the cited reference and her position that the pending claims and those in the cited reference are not patentably distinct from each other. Although the applicants maintain that the claims are patentably distinct and without acquiescing to the Examiner's position, the applicants have executed a terminal disclaimer to facilitate prosecution of this case. The terminal disclaimer has been signed by the undersigned attorney and is attached herewith. The pending claims should therefore be allowed.

Having addressed all issues raised by the Examiner, the applicants respectfully request that all pending claims be allowed.

The Examiner is invited to contact the undersigned attorney by at 612/332-5300 with any inquiry regarding this amendment.

Date: March 19, 2001

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903

Minneapolis, MN 55402-0903

(612) 332-5300

By:\_

Bruce E. Black

Reg No. 41,622

23552
PATENT TRADEMARK OFFICE



9/688,221 **PATENT** E. LEARY
1623 FOR THE TOTAL THE TOTA

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

HELLER ET AL.

Examiner:

Serial No.:

09/688,221

Group Art Unit:

Filed:

September 22, 2000

Docket No.:

Title:

SUBCUTANEOUS GLUCOSE ELECTRODE

#### MARK-UP VERSION OF SPECIFICATION AMENDMENT

#### Page 10, line 15 through page 10, line 31

Useful redox polymers and methods for producing the sensing layer are described, for example, in U.S. Pat. Nos. [ (matter 3, 4, 5, 7, 8)] 5,264,104; 5,356,786; 5,262,035, and 5,320,725. Additional redox polymers include, for example, poly(1-vinyl imidazole); poly(4-vinyl pyridine); or copolymers of 1-vinyl imidazole such as poly (acrylamide co-1-vinyl imidazole) where the imidazole or pyridine complexes with  $[Os (bpy)_2 Cl]^{+/2+}$ ;  $[Os (bpy)_2 Cl]^{+/2+}$  $(4,4'-dimethyl bipyridine)_2 Cl]^{+/2+}$ ; [Os (4,4'-dimethyl)phenanthroline)<sub>2</sub> Cl]<sup>+/2+</sup>; [Os (4,4'-cimethyoxy phenanthroline)<sub>2</sub> Cl] $^{+/2+}$ ; and [Os (4,4'-dimethoxy bipyridine)<sub>2</sub> Cl] $^{+/2+}$ ; to imidazole rings. The imidazole ring compounds are preferred because their complexes have more reducing redox potentials, i.e., closer to that of the SCE potential. At these more reducing potentials, the rate of electrooxidation of interferants and the current generated thereby.

#### Page 11, line 23 through page 12, line 2

When a separate interferant eliminating layer is used, it preferably contains a peroxidase enzyme which may or may not be preactivated. Such interferant eliminating layers are disclosed, for example, in U.S. Pat. No. 5,356,786 [(matter 4)  $\_$  and U.S. Patent Application No. 08/161,682] which discloses the structure and function of interferant eliminating biosensors. The glucose biosensor preferably contains lactate oxidase (LOX) in combination with peroxidase in the interferant eliminating layer. However, for biosensors used to detect lactate, glucose oxidase would be used with peroxidase. In a similar manner, the enzyme composition of the interferant eliminating layer may be altered for a specified function.

## Page 16, line 34 through page 17, line 3

In addition to implanting the sending electrode in the body, fluid from the body, particularly fluid from the subcutaneous region, can be routed to an external sensor. it is preferred in this case to implant in the subcutaneous region a microfiltration giver and pull fluid to an evacuated container, the fluid traversing a cell containing the sensing electrode. Preferably this cell also contains a second electrode, e.g., a reference electrode which may serve also as a counter electrode. Alternatively, the reference and counter electrodes may be separate electrodes. In coulometric measurements only two electrodes, the sensing electrode and the counter electrode are required. The flow of body fluid may [amy] be pulsed or continuous. Other than an implanted microfiltration fiber, also a microdialysis fiber may be used, preferably in conjunction with a pump.

